

Attorney Docket. No.: P61750US0

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Albrecht WENDEL et al.

Serial No.: 08/996,768

Group Art Unit: 1645

Filed: December 23, 1997

Examiner: J. Hines

Title: TEST PROCEDURE WITH BIOLOGICAL SYSTEM

AMENDMENT

Commissioner of Patents
Washington, D.C. 20231

Sir:

The instant paper responds to the Office Action mailed December 7, 2001.

IN THE CLAIMS

Cancel claims 19-25 and 27-29, without prejudice or disclaimer, and add the following claims.

30. A method for determining the reaction of blood to test materials and objects for human applications, the method comprising the steps of

- contacting the material or object with a sample of whole blood from human or animal donors for a period in a manner required to produce an immunofunctional, toxic, and/or modulatory reaction, wherein the sample of whole blood is a thawed cryopreserved unit of whole blood that contains an anticoagulant, said cryopreserved unit being one of a large number of identical cryopreserved units of one lot of whole blood containing said anticoagulant, and

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- detecting and/or measuring the immunofunctional, toxic, and/or modulatory reaction of the sample of whole blood to said material or object by biological, physical, chemical, and/or physicochemical methods to determine the reaction of blood.
31. The method according to claim 30 for detecting and/or measuring the immunofunctional reaction.
32. A blood sample comprising a cryopreserved unit of whole blood, wherein said cryopreserved unit is selected from the group consisting of a plurality of identical cryopreserved units from one lot of a whole blood sample, and wherein said cryopreserved unit is in the form of a standardized blood unit dose.
33. The blood sample according to claim 32, further comprising clotting inhibitors and/or diluents.
34. The blood sample according to claim 32, further comprising clotting inhibitors.
35. The blood sample according to claim 32, further comprising diluents.
36. In a method of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object comprising (i) contacting said material or object with a blood sample from a human or animal and (ii) detecting and/or measuring the immunofunctional, toxic, or modulatory blood reaction by a biological, physical, chemical, or physicochemical method, the improvement wherein the blood sample is a thawed cryopreserved unit in accordance with claim 32.

no object =
determine reaction

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37. In a method of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object comprising (i) contacting said material or object with a blood sample from a human or animal and (ii) detecting and/or measuring the immunofunctional, toxic, or modulatory blood reaction by a biological, physical, chemical, or physicochemical method, the improvement wherein the blood sample is a thawed cryopreserved unit in accordance with claim 33.
- C 1 38. In a method of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object comprising (i) contacting said material or object with a blood sample from a human or animal and (ii) detecting and/or measuring the immunofunctional, toxic, or modulatory blood reaction by a biological, physical, chemical, or physicochemical method, the improvement wherein the blood sample is a thawed cryopreserved unit in accordance with claim 34
39. In a method of testing a material or object for human applications by detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object comprising (i) contacting said material or object with a blood sample from a human or animal and (ii) detecting and/or measuring the immunofunctional, toxic, or modulatory blood reaction by a biological, physical, chemical, or physicochemical method, the